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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/575,913 | 11/16/2006 | John Brew | GJE-7489 | 5107 |
| 23557 7590 12/09/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | | |
| EXAMINER | | | | |
| CRUZ, KATHRIEN ANN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1617 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 12/09/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,913

Applicant(s)

BREW ET AL.

Examiner

KATHRIEN CRUZ

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date 11/15/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-17 are presented for examination.

Claim Rejections - 35 USC § 112

Claims 8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 and 16 are not clear what are the "compounds that cause uptake blockade". The instant specification does not disclose any compounds that cause uptake blockade. Therefore, one skilled in the art would not know which compounds would cause uptake blockade.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (WO 99/44610).

Boyce teaches a method for the treatment of pain or nociception by administering NMDA antagonist such as eliprodil or ifenprodil and an amount of an opioid analgesic together so that they give effective pain relief to a patient in need thereof (claims 2 and

7). Boyce teaches that NMDA antagonist such as eliprodil or ifenprodil and an amount of an opioid analgesic may be used to treat migraines, headaches and trigeminal neuralgia, pain associated with cancer, peripheral neuropathy, rheumatoid arthritis and other forms of chronic pain (page 4 line 30 – page 5, line 10). Boyce teaches that NMDA antagonist such as eliprodil or ifenprodil and an amount of an opioid analgesic may be administered by inhalation or insufflation (page 8, line 6).

With regards to intermittent or episodic pain as set forth in claim 1; it is inherent that in the treatment of pain would encompass both intermittent and episodic pain since administration of NMDA antagonist such as eliprodil or ifenprodil and an amount of an opioid analgesic together so that they give effective pain relief to a patient in need thereof treats **all** types of pain.

Claims 1, 10 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Caruso (U.S. Patent 6,007, 841).

Caruso teaches a method of alleviating pain by administering a narcotic (i.e. buprenorphine or nalorphine) and an NMDA antagonist (claims 12 and 13). Caruso teaches that NMDA antagonist and a narcotic such as buprenorphine or nalorphine may be administered via **intranasal**, for example, a liquid spray, as a powder or in the form of drops (column 4, lines 41-43). Caruso teaches topical administration in the mouth, the NMDA antagonist and a narcotic such as buprenorphine or nalorphine composition may take the form of buccal or **sublingual tablets**, drops or lozenges formulated in conventional manner (column 4, lines 3-6).

Conclusion

Claims 1-17 are rejected.

No claims allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617